510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K122534

B. Purpose for Submission:

New submission for quality control material

C. Measurand:

Prostate specific antigen (PSA)

D. Type of Test:

Fluorescence immunoassay

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

IMMULITE/IMMULITE 1000 third Generation PSA calibration Verification Material

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1660 Quality Control Material (assayed and unassayed)

2. Classification:

   Class I

3. Product code:

   JJX Single (specified) analyte controls (assayed and unassayed)

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   The IMMULITE®/IMMULITE 1000 Third Generation PSA Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of PSA antigen.

2. Indication(s) for use:

   Same as Intended Use

3. Special conditions for use statement(s):

   Prescription use only.

4. Special instrument requirements:

   IMMULITE®/IMMULITE 1000 Systems

I. Device Description:

The Calibration Verification Material (CVM) contains one set of four vials of 4 different concentrations of PSA, 3 mL each. L3PSCVM1, without PSA, contains processed chicken serum matrix with preservative. L3PSCVM2, L3PSCVM3 and L3PSCVM4 contain low, intermediate and high levels of PSA respectively, in processed chicken serum matrix with preservative.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Access Hybritech p2PSA QC
2. Predicate 510(k) number(s):

   k112603
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The IMMULITE®/IMMULITE 1000 Third Generation PSA Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of PSA antigen.	The Access Hybritech p2PSA QC are tri-level controls intended for monitoring system performance of immunoenzymatic procedures for the quantitative measurement of [-2]proPSA isoform of Prostate Specific Antigen (PSA) using the Access Immunoassay Systems.
Function	Quality Control material	Same
Reagent form	Liquid	Same
Traceability	Internal Reference Preparation	Internal reference preparation
Stability	Stable until the expiration date when stored frozen.	Stable until the expiration date when stored frozen.

Differences		
Item	Device	Predicate
Storage Condition	-20ºC	-20°C or colder
Reagent Matrix	Buffering salts and Processed (pH-treated) Chicken Serum	Buffering salts and bovine serum albumin
Antigen source	PSA	[-2]proPSA isoform of Prostate

Differences		
Item	Device	Predicate
		Specific Antigen (PSA)

K. Standard/Guidance Document Referenced (if applicable):

1. CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
2. Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
3. Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

L. Test Principle:

The reagent material has no inherent test principle but is used to monitor the performance of a fluorescence immunoassay for the quantitative measurement of PSA in human serum.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

IMMULITE Third Generation PSA assay is traceable to an internal standard manufactured using qualified materials and measurement procedures. The Calibration Verification Material (CVM) is traceable to this standard.

Value assignment: The PSA concentration levels are value assigned using an approved reference lot manufactured with qualified materials and measurement procedures. The reagent PSA concentrations were tested using a total of 27 replicates per level; 9 runs and 3 replicates per run. 2 different kit lots and 9 different instruments were used to gain the 27 replicates per level of the reagent. The analyte values were calculated based on the recovered values for each run independently. The average analyte value recovered for each PSA concentration determined the assigned value (Target Mean) ± 2 Standard Deviation (SD) units.

Expected Values: The expected values are provided in the IMMULITE®/IMMULITE 1000 PSA Calibration verification Material lot-specific value sheet. The expected assay range is 0.015 - 20 ng/mL. Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative total precision, tabulated in the respective assay instructions for use, may be considered as one factor when establishing local, acceptable ranges. The values below can be considered as guidelines.

Level	Catalog and Lot number	Target Mean (ng/mL)	SD	Guideline Range (ng/mL)	
1	L3PSCVM1 D101	0.000		≤ 0.005	
2	L3PSCVM2 D101	0.085	0.0065	0.072	0.098
3	L3PSCVM3 D101	4.45	0.2225	4.01	4.90
4	L3PSCVM4 D101	18.6	1.4	15.8	21.4

Stability: The calibration verification reagent is stable until the expiration date (at least 90 days) when stored frozen at -20°C prior to opening. Discard after use.

The stability calibrators are run in duplicate (as a minimum) and the PSA concentration determined from reference calibrator curve. Real-time stability studies were performed for 3 lots of calibration verification material (CVM). The testing periods for one lot were 6 months and 12 months. The periods for a second lot were 1 day, 15 days, 30 days, and 120 days. The testing periods for the third lot were 1 day, 15 days, 30 days, and 90 days. The stability study shows acceptable results up to 90 days when stored at -20°C.

Evaluation of matrix effects: To investigate potential matrix effects from using Chicken Serum, spiking recovery of PSA was determined. A stock solution of calibrator grade prostate specific antigen (PSA) was utilized to prepare the concentrations of three spiking solutions. Concentrations were determined gravimetrically, refer to Table 1.

Table 1 Spiking solution concentration values

	Value of spike solution (ng/mL)
Stock 1	10.87
Stock 2	46.25
Stock 3	89.13

Each spiking solution was spiked into an evaluation lot and patient sample (1 part spiking solution to 19 parts matrix). The spiked samples were run in a PSA assay on one IMMULITE platform. The PSA values of the evaluation lot were compared to the patient sample lots. Each of the samples meets the acceptance criteria of mean recovery being within ±15% of the target and the grand mean is within ±10% of reference. Since there were no significant differences between the evaluation lot and patient sample lots, it was concluded that the spiking recovery has shown no matrix effects.

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

See above target expected values for each PSA concentration.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.